REMARKS

Status of the Claims

The Applicant wishes to thank the Examiner for the teleconference of July 03, 2008 regarding submission of this paper to replace the Response filed June 21, 2008. Please disregard Response filed June 21, 2008.

Claims 45-66 were pending. Claim 63 has been amended. New claims 67-70 have been added. The Applicants respectfully point out that the Action recites that claims 45-65 are pending, but claims 45-66 were pending at the time of the restriction.

No new matter has been added.

Amendment to the Claims

Claim 63 has been amended to correct a typographical error.

New claims 67-70 have been added. Support for these claims can be found through out the specification but at least at paragraphs {0015], [0016], [0018], [0027], [0028], [0031], [0032], [0034], [0035], [0045], [0049], [0051], [0061], [0064], [0071], [0077], [0082], [0091], [0102] and [0107] of the application as originally filed.

Traversal of Restriction Requirement

The Action imposed a 2-way restriction requirement as follows: Group I, claims 45-62 and 64-66 are drawn to methods for analyzing effector or regulator cell cycling to determine when an agent should be administered to a patient suffering from a disease characterized by the production of regulator cells, and a kit for use in such a method; and Group II, claim 63, is drawn to methods for diagnosing a disease characterized by the production of regulator cells through analyzing effector or regulator cell cycling. Applicant respectfully traverses the restriction requirement.

On page 2, the Action asserts "The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT rule 13.1 because under PCT rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature of these inventions is the measure of regulator or effector cell cycling. methods involving making such determinations are known in the prior art. See e.g. WO 02/13828 …claims 1, 2 and 10 (indicating that timing of pharmaceutical agents is determined by regulator or effector cell cycling)

The inventions therefore lack a common special feature over the prior art." The Applicant disagrees with this assertion.

The Applicant submits that the cited reference (WO 02/13828) relates to resetting the immune system and targeting expanding regulator cells while maintaining effector cells. In contrast, the instant application is based on a surprising finding that the immune system is constantly cycling in disease states such as cancer and chronic infections. As a consequence, when compared to WO 02/13828, the instant application does not disclose "resetting" of an immune system but rather, the instant application is based on "analyzing effector cell and/or regulator cell cycling," elements of independent claims 45, 46, and 63-66. Thus, the pending claims clearly share a single general inventive concept and Groups I and II should be rejoined.

Provisional Election

On page 3, the Action further restricts the groups to electing species. The Action asserts that election of Groups I or II require one of the listed embodiments (a) through (g) and for only Group I, one of (i) cancer or (ii) an infection and finally for claim 48 one of (A) through (D).

In the event that the Examiner reconsiders the restriction requirement and rejoins Groups I and II, Applicant provisionally elects (f) an immune system marker, (i) cancer (claims 47, 54 and 55) and (A) inhibits the production of regulator cells (claim 60).

If Groups I and II are not rejoined, then Applicant provisionally elects Group I, claims 45-62 and 64-66 are drawn to methods for analyzing effector or regulator cell cycling to determine when an agent should be administered to a patient suffering from a disease characterized by the production of regulator cells, and a kit for use in such a method. This election reads on claims 45-47, 49-51, 54, 55 and 60 and new claims 67-70.

CONCLUSION

For the reasons stated above, Applicants assert that the response is in compliance with response to the outstanding restriction. Please feel free to call the undersigned, if additional response is required.

Respectfully submitted,

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